Quantitative Fit Assessment of a Precontoured Fracture Fixation Plate: Its Automation and an Investigation on the Borderline Cases

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Abstract. Virtual methods to assess the fitting of a fracture fixation plate were proposed recently, however with limitations such as simplified fit criteria or manual data processing. This study aims to automate a fit analysis procedure using clinical-based criteria, and then to analyse the results further for borderline fit cases. Three dimensional (3D) models of 45 bones and of a precontoured distal tibial plate were utilized to assess the fitting of the plate automatically. A Matlab program was developed to automatically measure the shortest distance between the bone and the plate at three regions of interest and a plate-bone angle. The measured values including the fit assessment results were recorded in a spreadsheet as part of the batch-process routine. An automated fit analysis procedure will enable the processing of larger bone datasets in a significantly shorter time, which will provide more representative data of the target population for plate shape design and validation. As a result, better fitting plates can be manufactured and made available to surgeons, thereby reducing the risk and cost associated with complications or corrective procedures. This in turn, is expected to translate into improving patients' quality of life.

Introduction

Straight and anatomically precontoured metal plates are two of the internal fixators used for bone fracture treatments. Precontoured plates optimize the fitting between the plate shape and the bone contour at its designated location. Anatomical fitting of a precontoured plate allows easier reduction and correct alignment of bone fragments, and reduces the possibility of further complications or secondary corrective procedures. Despite having been used for a long time, quantitative analyses of precontoured plate fittings have only been studied recently [1-4]. These studies highlighted that current plates fit poorly for many patients.

The quantitative analysis of the fit between bones and anatomically pre-contoured plates is important for the design validation of the implant shape. In general, fit analysis is performed through manual fitting of an implant to a set of cadaver bones, where the fit is then qualitatively assessed. More recently, virtual quantitative methods were proposed for more accurate assessment of implant fitting, however with certain limitations such as simplified fit criteria or manual data processing [2,3]. In a study which employs a fully automated fit assessment procedure, the investigators used the average distance between the bone and plate to assess the plate fitting [3]. However, such a measurement is not clinically meaningful. To illustrate, at the local area where fit is required, the actual distance may be more than the tolerated value. However, this information cannot be communicated properly using the value of an average distance as a determination for plate fitting. Clinically relevant fit criteria and the ability to automatically process large bone dataset will greatly facilitate the development of optimal fitting implants for the intended patient populations. In another study, the investigators performed a semi-automated fit analysis procedure using clinical-based criteria [2]. However, data collection were performed manually, which requires long processing time and has higher possibility for error by the operator. By automating the process, accurate and speedy data collection is possible. Therefore, more time could be spent for extended data analysis to provide further information on an implant's fitting based on quantitative measures.

Regardless of the methods, previous studies on fit analysis had only divided their results into fit and no-fit cases [1-4]. Dividing the cases into fit and no-fit raises the question of whether there is a considerable number of borderline cases for which minor shape alteration would significantly improve the implant fitting.

Therefore, the aims of this study are twofold. First, to develop an automated fit analysis method based on clinical criteria, and then to compare its outcomes and processing time with a previously proposed semi-automated fit analysis method [2]. Second, to investigate the extent of borderline fitting cases for a tibia plate by performing extended analysis on the data collected based on the automated fitting method.

Materials and Methods

Materials. We used 3D models of a distal medial tibial plate and 45 computer tomography (CT) based Japanese tibiae, as well as four clinically-based criteria for fit analysis from a previous study [2].

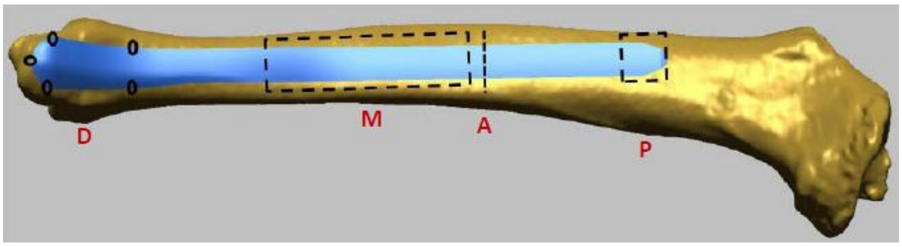

Fig. 1 The locations of the four fit analysis criteria for the distal tibial plate. The plate undersurface is shown in blue at the surgically correct position on the bone. Left to right: the five distal regions (D), the middle-third area (M), the proximal angle (A) and the proximal area (P) of the area of the plate.

Methods. Fit assessment were performed by obtaining the maximum plate-to-bone distance at the plate’s proximal, middle-third and five small areas in the distal regions, as well as the proximal angle, see Fig. 1. A Matlab (The Mathworks, Natick, MA) program to automate a fit analysis procedure and batch-process all 45 tibia-plate pairs was developed. The program executed the following tasks: first, the bone and plate models were imported as STL-files; next, the maximum plate-to-bone distance at the plate’s proximal region, middle-third region and five small areas in the distal region, as well as the proximal angle were calculated and evaluated for fit; finally, a report containing the measurements and fit analysis results was recorded on an Excel (Microsoft Corporation, Redmond, WA) spreadsheet. A global fit required all four criteria to be satisfied, where the maximum distance was ≤4mm (P), ≤6mm (M), ≤2mm (D) and a maximum angle of $\leq 10^{\circ}$ (A).

Comparison between the automated and semi-automated analyses. We compared the number of fit cases and the measurements performed at the four fit criteria regions between the semi-automated and automated procedures. In addition, we compared the processing time between the three major tasks, namely importing the 3D models, calculating the plate-tibia distance, and assessing fit criteria, in the automated fit analysis procedure.

Investigation on borderline cases. In order to investigate the borderline cases, the no-fit cases for each criterion were further grouped into specific tolerance ranges, see Fig. 4. The acceptable tolerance for borderline cases for each criterion was set to 4-5mm (P), 6-8mm (M), 2-3mm (D) and 10-12° (A).

Results and Discussion

Number of fit cases. The number of global fit cases was lower for the automated than the semi-automated method (2 and 6, respectively). The number of fit cases for each fit criterion were (automated vs. semi-automated): 28 vs. 28 (P), 29 vs. 27 (M), 11 vs. 18 (D), and 18 vs. 20 (A). The largest discrepancy was seen in the distal region. The conflicting cases in this region had at least one non fitting area amongst the five assessed areas, while the surrounding areas generally fit (Fig. 2, left). This highlights the difference between the two methods, in which the semi-automated method gives user the flexibility to make the final decision, while the automated method applies strict evaluation regardless of the clinical relevance of the conclusion. Applying strict assessment to the conflicting cases resulted in 6 of the 7 cases as not fitting in the distal region. The discrepancies in the middle-third and proximal angle fit criteria were mainly attributed to operator errors while performing the semi-automated method. In contrast, the automated method performs accurate and error-free operation for the analysis.

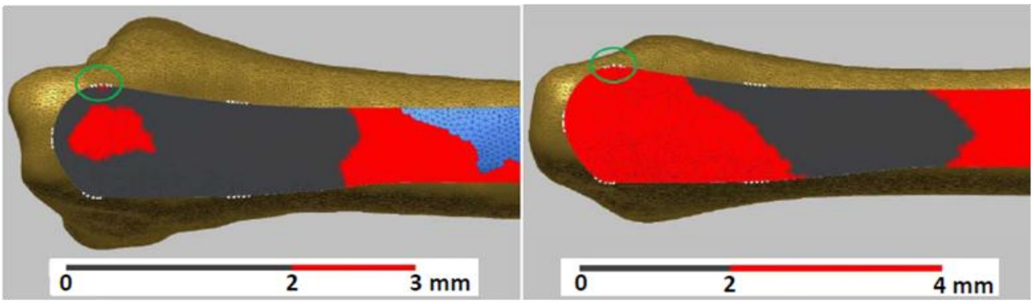

Fig. 2 Distance map for the distal fit criterion illustrating different types of no-fit cases. White dots indicate where the fit was analysed. Dark grey indicates fit, red indicates no fit. (Left) The green circle highlights a small portion of the analysed area that was not fitting, resulting in a no-fit case, although it was clinically acceptable as a fit case. (Right) All of the assessed area within the green circle and majority of the distal region was not fitting, therefore it was a clear no-fit case.

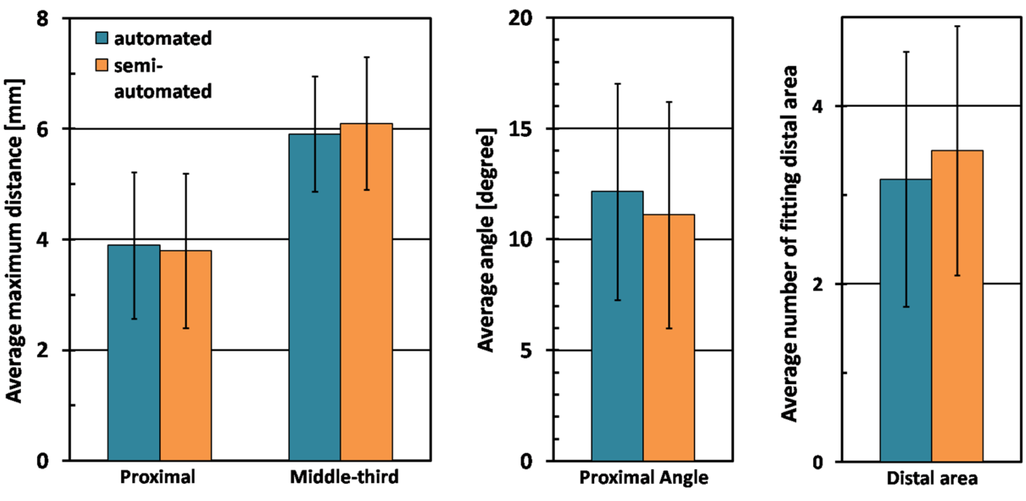

Fig. 3 Comparison of measurements recorded for the automated and semi-automated methods.

Measurements. The measurements were reasonably comparable between the automated and semi-automated methods (Fig. 3). The average maximum distances were 3.9±1.3mm and 3.8±1.4mm at the proximal region, and middle-third region were for 5.9±1.0mm and 6.1±1.1mm for the middle-third region for the automated and semi-automated methods, respectively. The number of fitting distal area were 2.7±1.2 and 3.5±1.4, while the proximal angle were 12.2±4.9° and 11.1±5.1° for the automated and semi-automated methods, respectively. The largest difference was again seen in the distal region where the number of fitting area differed by 1 area on average between both methods, which contributed to the discrepancy in the number of fit cases in the distal region as mentioned previously.

Table 1 The processing time for the three major tasks in the automated fit analysis method.

Task	Processing time[s]/plate-tibia
Importing models	1004.73 ±310.76
Calculating plate-bone distance	1.93±0.31
Assessing fit criteria	0.38±0.35

Processing time. The processing time was highest for importing the models into Matlab (Table 1). Excluding this task, the rest of the process was completed in ~3s, while it took 5-10min for the semi-automated method to process each plate-tibia pair. Further optimization to the code to import the models is expected to reduce the processing time significantly mainly because from experience, we found that commercial reverse-engineering software were able to import the same models within a few seconds.

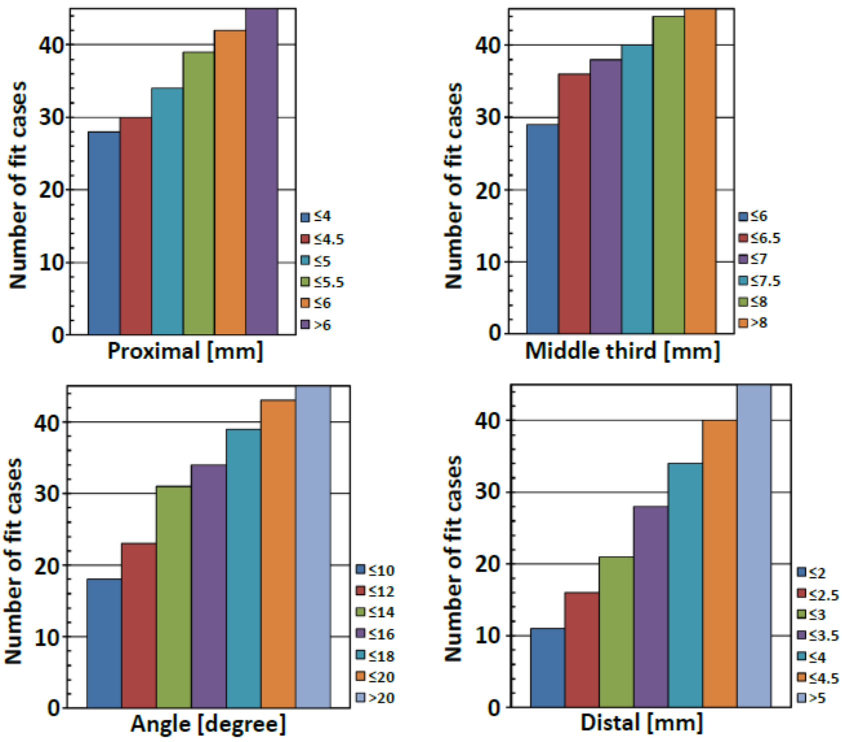

Fig. 4 The number of fit cases for all four fit criteria for different tolerance ranges.

Investigation on borderline cases. Based on the tolerance specified for borderline cases, the borderline group contained: 6 (P), 15 (M), 10 (D), and 5 (A) cases, resulting in 9 additional globally fitting cases. Six of the 7 cases that were fitting in the distal region using the semi-automated method but not fitting using the automated method were included in the borderline group for the distal region. Similarly, when the tolerances were relaxed for the borderline group, 3 of the 4 cases that globally fit using the semi-automated method but not fitting using the automated method were included within the 9 additional globally fitting cases for the borderline group.

Despite this significant increase, the fitting plus borderline cases only amount to approximately a quarter (n=11) of the dataset used, which still leaves at least 75% of bones where the plate did not fit. The graphs in Fig. 4 illustrate a gradual increase in fit cases with a relaxation of the fitting tolerances for each criterion. These results indicate that minor changes to the plate shape are inadequate to significantly increase the percentage of fit cases. This observation is confirmed by results of a study where a fit of 67% was achieved for the same dataset after significant alterations to the plate shape [4].

Conclusions

Automated plate fit analysis allows efficient analysis for large bone datasets through batch-process and short processing time. Although the number of global fit cases was different between the automated and semi-automated methods, the number of fit cases for each fit criterion were close except for the distal fit criterion where strict assessment was applied. To address this, we recommend that surgeons review the no-fit cases in order to draw clinically relevant conclusion. Nevertheless, through studying the borderline cases, we found that cases that were fitting using the semi-automated method but not fitting using the automated method fall under the borderline group. Therefore, by creating another group i.e. the borderline group, the clear no-fit cases can be distinguished from marginally fitting cases (Fig. 2). Hence, as an option, surgeons could then review these cases specifically as opposed to reviewing the entire set of no-fit cases.

Additionally, the results of the investigation on borderline cases also demonstrate that introducing a group for borderline cases can aid the process of implant design. Determining the number of borderline fit cases gives an indication of whether a minor shape change is sufficient or whether a major review of the plate design is required. In addition, reporting the number of cases in a specified borderline group will provide a more detailed and informed analysis of the no-fit cases.

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